



DEPARTMENT OF THE NAVY
NAVAL MEDICAL COMMAND
WASHINGTON, D.C. 20372-5120

IN REPLY REFER TO

NAVMEDCOMINST 6320.16
MEDCOM-00D3
23 Aug 88

NAVMEDCOM INSTRUCTION 6320.16

From: Commander, Naval Medical Command

Subj: INFORMED CONSENT FOR MEDICAL AND DENTAL TREATMENT

Ref: (a) Joint Commission on Accreditation of Hospital
Organizations Accreditation Manual for Hospitals

1. Purpose. To set forth the requirements for obtaining consent for all health care at naval medical and dental treatment facilities.

2. Background. With limited exceptions, every person has the right to be medically examined and treated only when and in the manner which they authorize. This individual right is the foundation of the consent requirement applicable to the practice of medicine and dentistry and is the basis for the concept that a competent adult patient has the right to make informed decisions about health care and treatment. Patients must be provided with appropriate disclosure of information because it is the proper thing for caring and compassionate health care professionals to do. Appropriate documentation must be provided that demonstrates that patients are properly informed concerning medical and dental treatment for the protection of the individual health care provider, as well as, institutional and governmental protection. Although the concept of informed consent originated as a part of tort law, reference (a) clearly makes it an issue of quality patient care.

3. Responsibilities

a. Commanding Officer. Commanding officers of all medical and dental treatment facilities (MTF/DTF) must ensure the spirit and intent of this instruction are carried out. To do so, the promulgation of facility-specific implementing instructions is required. The appropriateness of consent practices within the facility should be monitored as a regular part of the medical and dental records review.

b. Responsible Health Care Provider. Responsible health care providers must provide the patient counseling necessary to obtain informed consent for treatment and appropriately document that the process has occurred.

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4. Consent

a. General. The term "consent" in the health care setting refers to a patient's agreement to undergo an examination or treatment. The doctrine of "informed consent" is not limited to obtaining a patient's signature on a form, but rather it requires that the provider convey all information necessary for the patient to make a knowledgeable decision on the proposed procedure. The patient's agreement must be made with full awareness of the consequences of the agreement. If there is no such awareness, there is no informed consent. Documenting the information provided is an integral part of the process. Informed consent is best understood as a process which involves disclosure of information by responsible health care providers to a patient and a health care or treatment decision by the patient based upon the information received, with subsequent documentation by the responsible health care professionals. The process recognizes and respects a patient's autonomy in health care decision-making. Informed consent is not limited to surgical procedures. It is equally applicable to all areas of medical and dental treatment.

b. Information To Be Provided. After advising the patient of the nature of his or her condition, the provider must describe the proposed procedure in lay terms so the patient understands what is proposed. The material risks and expected benefits of the proposed course must be explained. The availability of alternative health care options, as well as the option of nontreatment, should be explained. A material risk is one that a reasonable person would be likely to consider significant in deciding whether to undertake therapy. Whether or not a risk is material is a function of the likelihood of occurrence, the severity of the injury it threatens to cause, as well as the existence of reasonable alternatives. A provider is not required to explain risks which are considered to be extremely remote unless:

(1) Explanation is requested by the patient; or

(2) The potential adverse consequences are of such gravity that a reasonable person in the particular circumstances of the patient would consider the risk important to the treatment decision despite its relatively low probability; or

(3) Because of the particular circumstances of this patient, which are known to the physician, the remote risk would be significant because of possible serious harm. Where the harm which could result is serious or the risk of harm is high, the duty to disclose is greater.

c. Manner of Informing the Patient. The above information must be provided in a manner that allows a patient of ordinary understanding who is faced with the choice of selecting among the alternatives or refusing treatment altogether, to intelligently weigh the risks and benefits. Health care providers must communicate in language which can be reasonably understood by the patient, considering the patient's actual communication skills. Although open discussions between the responsible health care provider and the patient should be the standard, methods may be developed within each department to acquaint patients with the benefits, risks, and alternatives to procedures that involve bodily contact and require consent. In some departments, prepared pamphlets or information sheets may be desirable. No uniform policy for all departments is possible or desirable.

d. Disclosure Not Required. There are two situations where disclosure of the material risks, expected benefits, and alternatives is not required.

(1) Patient Requests Not To Be Informed. When a patient specifically requests not to be informed of the material risks of a proposed procedure, disclosure is not required. Because this is an exception to the normal duty to disclose, extra attention in documenting the reason for nondisclosure is required.

(2) Therapeutic Privilege. If in the sound medical judgment of the attending provider, full disclosure of the material risks of a proposed procedure or course of treatment is likely to cause the patient to become ill or complicate the patient's condition, disclosure of risks is not required. These situations, however, will arise very infrequently. It is extremely difficult to overcome the strong presumption in favor of full disclosure. Accordingly, all cases are subject to prior review and consultation with the chief of service when withholding of information is contemplated under a claim of therapeutic privilege. A health record entry must be made which sets forth the rationale for nondisclosure. It must be made by the attending physician and counter-signed by the chief of service.

5. Types of Consent. Consent may be expressed or implied.

a. Express Consent. This type of consent is obtained through open discussion between the provider and the patient and must include a statement that consent is given for the proposed procedure. Express consent may be oral or written.

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(1) Oral Consent. Except where consent is specifically required by law to be in writing, oral consent is legally sufficient authorization for treatment. Oral consent, however, is difficult to prove. Situations where oral consent for treatment is received must be documented by a progress note or entry in the treatment record which fully discusses the factors addressed in paragraph 4. Consent received by competent authority by telephone is a form of oral express consent and should be witnessed by a person not directly involved in the care of the patient and documented by a progress note or entry in the treatment record.

(2) Written Consent. Properly prepared written documentation of consent reduces problems of proof. Consent is documented by having the patient sign all appropriate forms authorizing treatment and by including either a progress note or an entry in the treatment record which discusses the factors addressed in paragraph 4. Except in emergency situations written consent is required for surgery, anesthesia, reproductive procedures, and certain other specialized treatments. In some jurisdictions, State law requires written consent for specified procedures.

b. Implied Consent. Implied consent is that which arises by reasonable inference from the conduct of the patient even though specific words of consent may not be communicated. Implied consent can apply only when, because of the circumstances, it can reasonably be presumed the risks, benefits, and alternatives to treatment are known to the patient. For example, a patient's request for admission to a medical treatment facility (MTF) is an implied consent for hospitalization and a patient's presentation to dental sick call is an implied consent for a dental exam. Implied consent will never form the basis for treatment in:

- (1) Surgical cases or any invasive procedures.
- (2) Procedures where internal or external sources of radiation are used in the treatment of the patient.
- (3) Procedures which involve electroshock or drug therapy of a psychiatric condition.
- (4) Situations where a court order is required, such as sterilization of an incompetent.

6. Who May Consent. The determination of who has authority to consent to medical and dental treatment is based on an evaluation of the competence of the patient to understand the proposed medical or dental procedure and its alternatives. If competent to make health care decisions, the patient alone has authority to consent. In the absence of contrary evidence, adult patients presenting for treatment are presumed competent. If the patient is incompetent either by reason of statutory incompetency (e.g., a minor), or by reason of mental impairment, the inquiry must turn to who, if anyone, has the legal capacity to consent to treatment on behalf of the patient. Except in those situations where Federal court decisions or statutes have preempted State law, legal capacity to consent will normally be determined by the law of the State in which the facility is located. In overseas areas, if not regulated by treaty or status of forces agreements, the general guidance of this instruction will be followed.

a. Minor Dependents

(1) The 50 United States. While most states recognize 18 as the age of majority, there are numerous variations in laws regarding consent by minors. Examples of some of these variations are: Emancipated Minors' Acts; service with the Armed Forces; and provisions allowing consent to treatment for venereal disease, drug addiction, pregnancy, and birth control (but not sterilization). Commanding officers must ensure that consent protocols for their facilities are consistent with the law of the jurisdiction in which their command is located. Where it has been determined a minor has the legal capacity to consent, health care providers are encouraged to make a sincere effort to persuade the minor to permit the provider to notify the parent or sponsor. This is particularly appropriate when, in the professional judgment of the provider:

(a) Severe complications are present or are anticipated.

(b) Major surgery or prolonged hospitalization is anticipated.

(c) Failure to notify would jeopardize the safety and health of the minor patient.

(d) To inform would benefit the minor's physical and mental health and family harmony.

(2) All Areas Outside The 50 United States. In those overseas areas where no applicable law exists on the subject, the following provisions will be followed:

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(a) Outpatient Treatment For Venereal Disease, Drug and Alcohol Abuse, and Birth Control (excluding sterilization and abortion). If the attending health care provider is satisfied that the dependent minor is sufficiently mature to understand the seriousness of his or her medical condition and the risks and benefits of treatment, the consent of the minor dependent is sufficient to provide treatment. No notice to or consent from the parent or sponsor will be required or permitted.

(b) All Other Cases. Except in emergency situations as discussed in paragraph 7, the consent of the parent or guardian must be obtained in all cases prior to treatment of minor dependents.

b. Parent or Guardian. The parent or guardian of the minor has the legal capacity to consent to the treatment of the minor. Such consent must be obtained except in emergency situations and the special circumstances described in the above paragraph. Where parents have joint custody, consent of one parent is sufficient. In the case of a legal separation or divorce, the consent of the parent with custody of the child is usually required.

c. Written Authorization. When the parents or guardian of the minor are not available, but they have stated, in writing, that the person in care, custody, or possession of the minor can give consent, such authorization may be accepted.

d. Telephone Authorization. When the parents or guardian of the minor are not physically available, but may readily be reached by telephone, authorization for the treatment of that minor may be obtained by telephone as long as the authorization is witnessed by a person not directly involved in the care of the minor and is documented in the medical record.

e. Incompetent Adults. When a judicial determination of incompetence to make treatment decisions has been made, consent must be obtained from the person appointed by the court to act for the incompetent patient. When the responsible physician or dentist believes that an adult patient is incompetent, either temporarily or permanently and emergency treatment is not required, treatment should be withheld pending consent from the person who is authorized to consent for the patient. Absent a judicial determination of incompetence, spouses, adult children, parents, and siblings should be the order of priority in providing third-party consent on behalf of mentally incompetent patients.

7. Emergency Situation. Consent prior to treatment is not necessary when immediate treatment is required to preserve life, prevent deterioration or aggravation of the patient's condition, and it is not possible to obtain the consent of the patient or person authorized to consent for the patient. The existence and scope of the emergency should be adequately documented by the provider, and it should be stated why the emergency precluded obtaining consent.

8. Documentation. Regardless of the method used to inform the patient, or the form of consent, the provider must make detailed progress notes of the disclosure and the patient's reactions in the medical or dental record. The progress note, written to document the disclosure of information to the patient, must be specific concerning the information provided. An entry which merely states the risks and benefits of the proposed treatment have been discussed with the patient is of little value. The risks, alternative forms of treatment, and expected benefits which were discussed with the patient must be specifically enumerated. This must be done even when the patient has signed a preprinted "consent" form. In conjunction with progress notes, SF 522, Request for Administration of Anesthesia and for Performance of Operations and Other Procedures, will continue to be used to document consent in all surgical and anesthetic procedures other than local dental anesthesia and routine restorative dentistry. Special attention must be given to documenting a patient's request to not be informed of risks and alternatives to planned treatment.

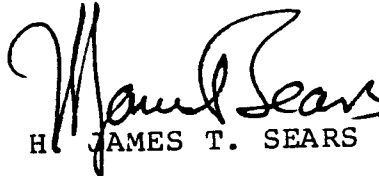
9. Witness to Consent. Anyone over the age of majority may witness the documentation of consent. The witness should be a member of the health care facility who is not participating in the procedure or treatment. Relatives of the patient are not advisable as witnesses. A witness is required on all consent forms. The witness is confirming that the patient signed the form, but does not necessarily indicate that all relevant information was given to the patient.

10. Duration of Consent. Consent is valid as long as no material change in circumstances occurs between the date that consent was given and the date of the procedure or treatment. New consent must be obtained if a material change in circumstances has occurred.

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11. Form. SF 522 (10-76), Request for Administration of Anesthesia and for Performance of Operations and Other Procedures, NSN 7540-00-634-4165, is available from the Federal Supply System through normal supply procurement procedures.


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